General

Guideline Title

ACR Appropriateness Criteria® breast cancer screening.

Bibliographic Source(s)

Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, D'Orsi C, Harvey JA, Hayes MK, Huynh PT, Jokich PM, Lee S, Lehman CD, Mankoff DA, Nepute JA, Patel SB, Reynolds HE, Sutherland ML, Haffty BG, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® breast cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 5 p. [28 references]

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

ACR Appropriateness Criteria®

Clinical Condition: Breast Cancer Screening

Variant 1: High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between the ages of 10 to 30, women with 20% or greater lifetime risk of breast cancer.

Radiologic Procedure	Rating	Comments	RRL*
Mammography screening	9	Beginning at age 25-30 or 10 years before age of first-degree relative with breast cancer or 8 years after radiation therapy, but not before age of 25. Mammography and MRI are complementary examinations, both should be performed.	
MRI breast with and without contrast	9	Beginning at age 25-30 or 10 years before age of first-degree relative with breast cancer or 8 years after radiation therapy, but not before age of 25. Mammography and MRI are complementary examinations, both should be performed. See	

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
		statement regarding contrast in text under "Anticipated Exceptions."	
US breast	6	If patient cannot have MRI.	O
FDG-PEM	2		
Tc-99m sestamibi BSGI	2		
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, dense breasts, or 15% to 20% lifetime risk of breast cancer.

Radiologic Procedure	Rating	Comments	RRL*
Mammography screening	9		
MRI breast without and with contrast	7	See statement regarding contrast in text under "Anticipated Exceptions."	O
US breast	5		O
FDG-PEM	2		
Tc-99m sestamibi BSGI	2		
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Average-risk women: women with <15% lifetime risk of breast cancer, breasts not dense.

Radiologic Procedure	Rating	Comments	RRL*
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative

Mammography screening Radiologic Procedure	9 Rating	Comments	RRL*
MRI breast without and with contrast	3		O
US breast	2		O
MRI breast without contrast	1		O
FDG-PEM	1		
Tc-99m sestamibi BSGI	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Mammography

Mammography is the only method of screening for breast cancer shown to decrease mortality. Annual screening mammography is recommended starting at: 1) age 40 for general population; 2) age 25-30 for BRCA (BReast CAncer 1) carriers and untested relatives of BRCA carriers; 3) age 25-30 or 10 years earlier than the age of the affected relative at diagnosis (whichever is later) for women with a first-degree relative with premenopausal breast cancer or for women with a lifetime risk of breast cancer ≥20% on the basis of family history; 4) 8 years after radiation therapy but not before age 25 for women who received mantle radiation between the ages of 10-30; and 5) any age for women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS), or invasive breast cancer. However, mammography alone does not perform as well as mammography plus supplemental screening in certain subsets of women, particularly those with a genetic predisposition to the disease and those with dense breasts. Therefore, supplemental screening is recommended in selected high-risk populations.

Magnetic Resonance Imaging

Breast magnetic resonance imaging (MRI) in high-risk women has been shown to have a higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity. In a high-risk population, MRI and mammography combined have a higher sensitivity (92.7%) than ultrasound (US) and mammography combined (52%). Therefore, in high-risk women for whom supplemental screening is indicated, MRI is recommended when possible.

Screening high-risk women with breast MRI is cost-effective and the cost-effectiveness of screening MRI increases with increasing breast cancer risk. The American Cancer Society recommends screening breast MRI in certain high-risk women, and the American College of Radiology (ACR) and Society of Breast Imaging endorse those recommendations. Screening MRI is recommended in women with BRCA gene mutations and their untested first-degree relatives as well as women with a lifetime risk of breast cancer of ~20% or greater. Also included in this high-risk group are women who have received radiation therapy to the chest between the ages of 10-30 as well as women with other genetic syndromes that increase the risk of breast cancer (e.g., Li Fraumeni syndrome). For other women with an intermediate risk of breast cancer, such as those with a lifetime risk of 15% to 20%, a personal history of breast cancer, or a history of lobular neoplasia or ADH, the use of screening MRI is an area of ongoing investigation. However, recent literature supports the use of screening MRI in addition to mammography in patients with a personal history of breast cancer and lobular neoplasia.

Ultrasound

Screening US is indicated in high-risk patients who cannot tolerate MRI. Supplemental screening with US for women with intermediate risk and dense breasts is an option. However, hand-held US screening by the radiologist has a high false-positive rate and is time-consuming. Therefore,

this is likely not a cost-effective practice.

Other Imaging Modalities

There is insufficient evidence to support the use of other imaging modalities such as thermography, breast specific gamma imaging (BSGI), positron emission mammography (PEM), or optical imaging for breast cancer screening. Radiation dose from BSGI and PEM are 15-30 times higher than the dose of a digital mammogram, and they are not indicated for screening in their present form.

Summary

- For high-risk women, annual screening mammography and contrast-enhanced MRI are both indicated. US can be used for patients with contraindications to MRI.
- For intermediate-risk women, annual screening mammography is indicated. Contrast-enhanced MRI may be indicated in some patients.
- For average-risk women, annual screening mammography is indicated.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- BRCA, breast cancer
- BSGI, breast specific gamma imaging
- MRI, magnetic resonance imaging
- FDG-PEM, 18F-fluorodeoxyglucose–positron emission mammography
- Tc, technetium
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Breast cancer

Guideline Category

Prevention

Risk Assessment

Screening

Clinical Specialty

Family Practice

Obstetrics and Gynecology

Oncology

Preventive Medicine

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic examinations for breast cancer screening

Target Population

- Women at high-risk of breast cancer
- Women at intermediate risk of breast cancer
- Women at average risk of breast cancer

Interventions and Practices Considered

1. Mammography screening
2. Magnetic resonance imaging (MRI) breast
    - Without and with contrast

    - Without contrast
3. Ultrasound (US) breast
4. 18F-fluorodeoxyglucose–positron emission mammography (FDG-PEM)
5. Technetium (Tc)-99m sestamibi breast specific gamma imaging (BSGI)

Major Outcomes Considered

Utility of radiologic examinations in differential diagnosis

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

- Screening high-risk women with breast magnetic resonance imaging (MRI) is cost-effective and the cost-effectiveness of screening MRI increases with increasing breast cancer risk.
- Screening ultrasound (US) is indicated in high-risk patients who cannot tolerate MRI. However, hand-held US screening by the radiologist has a high false-positive rate and is time-consuming. Therefore, this is likely not a cost-effective practice.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for breast cancer screening

Potential Harms

Hand-held ultrasound (US) screening by the radiologist has a high false-positive rate and is time-consuming.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the ACR Manual on Contrast

Media (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, D'Orsi C, Harvey JA, Hayes MK, Huynh PT, Jokich PM, Lee S, Lehman CD, Mankoff DA, Nepute JA, Patel SB, Reynolds HE, Sutherland ML, Haffty BG, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® breast cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 5 p. [28 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

Electronic copies of the updated guideline: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site .

- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 92 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria® breast cancer screening. Evidence table. Reston (VA): American College of Radiology; 20 p. Electronic copies: Available in PDF from the ACR Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 21, 2012.

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